

**Remarks/Arguments:**

**35 U.S.C. § 103(a)**

***Guest in view of Dalton or Andersen***

Claims 1-5, 7-11, 13-22, 24, and 25 were rejected under 35 U.S.C. § 103(a) as being unpatentable over United States Patent 4,795,439 to Guest (Guest) in view of United States Patent 4,681,570 to Dalton (Dalton) or United States Patent 4,813,925 to Andersen, Jr. et al. (Andersen). The applicants respectfully traverse this rejection and submit that the claims are patentable over Guest in view of Dalton and Guest in view of Andersen because there is no motivation for the proposed combinations.

Guest discloses a multi-lumen catheter for use in a vessel that incorporates a spiraling feature only with respect to its internal structure. See column 2, lines 7-13. Its outer configuration is essentially that of a straight tube. See Figure 2. There is no teaching or suggestion presented by Guest of a corkscrew-patterned tubular structure.

Dalton, on the other hand, discloses a single lumen peritoneal catheter that takes the form of a flexible, elongated, perforated tube in a cylindrical helix configuration with its perforations along the tube wall. Dalton does not teach or suggest a multi-lumen catheter. The device taught by Dalton is essentially a long-term catheter implanted for repeated use in the peritoneal cavity. See column 2, lines 6-11. It achieves dialysis by "flooding the peritoneal cavity with a sterile dialyzing fluid, allowing the fluid to absorb toxins from the blood stream by osmosis through abdominal capillaries, and then draining the spent fluid from the cavity." See column 1, lines 10-23. Dalton recognizes that its distal terminus (27) may be closed or open, but is preferably restricted or entirely closed in order to "force the flow of fluid... primarily through perforations (23)."

Andersen discloses a single lumen ureteral stent. The stent has a helical, coiled structure for the purpose of maintaining an upon ureteral passage. See column 5, lines 9-12. The stent has no perforations along the length of the stent. Indeed, lengthwise perforations would substantially hinder an object of the invention which is deliver infusion fluid to the renal pelvic area (28) via the proximal end (25) of the device. See column 5, lines 16-30; Figure 8.

In contrast, the applicants' invention, as claimed, is a multi-lumen catheter having at least a portion of its outer tubular structure spirally formed into a corkscrew pattern and having a septum that divides the interior into at least a first lumen and a second lumen (see Figures 2A and 2B; page 6, lines 11-30).

The applicants respectfully submit that there is no teaching or suggestion for either reference to adopt or be combined with the structure disclosed in the other reference. Specifically, there is no suggestion to combine features of the device disclosed by Guest, a straight, multi-lumen vessel catheter, which is used for simultaneously introducing and removing fluids into and out of the bloodstream, with features of the Dalton single lumen peritoneal catheter, which is used to successively irrigate and drain an abdominal cavity, or the features of the Andersen single lumen stent used to flush the ureter. Likewise, because the Dalton device is not used for simultaneously introducing and removing fluids, there would be no reason to modify such a device to provide multiple lumens, as is taught in Guest. Dalton seeks to provide a catheter "suitable for implantation and long-term use in the peritoneal cavity"

(column 2, lines 6-9) and teaches that the pressure in the tube impels the helix to unwind, which "tends to free the tube perforations from organic deposits." (column 2, lines 19-23). The Guest catheter is not intended for implantation and long-term use, and Guest says nothing about organic deposits that would suggest modification to provide the helical core taught by Dalton. Accordingly, there is no teaching, suggestion or incentive supporting the combination of these references.

In *Ex parte Metcalf*, 67 U.S.P.Q.2d 1633 (May 2, 2003), the USPTO Board of Patent Appeals and Interferences cited caselaw to stress that there must be objective motivation to support an obviousness rejection. More specifically, the mere fact that teachings found in the prior art could be combined as proposed by an examiner does not make the combination obvious "absent some teaching, suggestion or incentive supporting the combination." *Id.* at 1635 (citing *Carella v. Starlight Archery and Pro Line Co.*, 231 USPQ 644, 647 (Fed. Cir. 1986)). It is respectfully submitted that the Examiner has failed to identify any such teaching, suggestion, or incentive to support the proposed combination. Accordingly, it is respectfully submitted that claim 1 is patentable over Guest and Dalton and Andersen, taken singly or in combination. Likewise, it is respectfully submitted that claims 2-24, which ultimately depend from claim 1, are also patentable over Guest and Dalton and Andersen.

In particular, the applicants respectfully submit that claim 19 recites an embodiment of the applicants' invention for which neither Guest nor Dalton nor Andersen, taken singly or in combination supply the requisite motivation to be combined. Specifically, claim 19 recites "[t]he catheter of claim 18, wherein the catheter is a hemodialysis catheter." Although Guest discloses "introducing medication or other fluids into a patient and/or removing blood from a patient at the same time" (column 1, lines 11-14), it does not teach or suggest hemodialysis which is the process of removing waste from the bloodstream. Further, while Dalton does mention hemodialysis in its disclosure it does so in the context of pointing out that the process is "not without difficulties" and that "peritoneal dialysis has gained favor in the management of renal failure." See column 1, lines 10-14. Finally, Andersen makes no mention at all of hemodialysis. For this reason, as well as the reasons outlined above, the applicants respectfully submit that claim 19 is patentable over the cited prior art.

#### ***Dalton in view of Guest further in view of Fenton***

Claim 12 was rejected under 35 U.S.C. § 103(a) as being unpatentable over Dalton in view of Guest further in view of United States Patent 5,190,520 to Fenton, Jr. et al. (Fenton). The applicants respectfully traverse this rejection and submit that the claims are patentable over the cited references.

As above, the applicants respectfully traverse the rejection because there is no teaching or suggestion to combine the Dalton and Guest references. Moreover, the applicants' invention, as recited in claim 12, includes a feature that is neither disclosed nor suggested by Dalton, Guest, or Fenton taken individually or in combination. Claim 12 depends from claim 10 and adds the following feature:

wherein the first lumen extends distally further than a distal end of the second lumen.

The applicants' respectfully submit that the Office Action errs in its characterization of Fenton when it describes it as illustrating one lumen extending beyond an adjacent lumen. The applicants respectfully submit that, at best, Figure 1 in Fenton depicts a double lumen catheter incorporating a divider that extends beyond the opposing inflection points of the catheter's tubular outer wall to form a pointed midsection. This may be better understood when read in light of the (albeit scant) Fenton specification which indicates that "[t]he method [of manufacture] may further include the step of shaping the distal end of the catheter to produce a formed tip." See column 3, lines 21-23. The applicants respectfully submit that the best interpretation of the phrase "formed tip" is one having a pointed midsection.

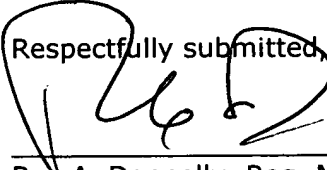
Because the distal tip disclosed by Fenton does not teach or suggest an extended lumen as recited by the applicants' claim 12, the applicants respectfully submit that *prima facie* obviousness cannot be established based on the cited references. Thus, the applicants respectfully submit that this distinction presents a basis for allowing claim 12.

Finally, the applicants respectfully traverse the rejection of claim 23. Claim 23 depends directly from claim 1 and incorporates each of its limitations. The applicants respectfully submit that claim 23 is allowable over the cited references for at least this reason.

### **Conclusion**

For at least the foregoing reasons, the applicants respectfully submit that pending claims 1-5 and 7-25 are allowable over the cited art. A notice to this effect is respectfully requested.

Respectfully submitted,

  
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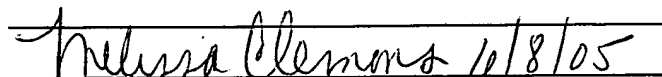
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